APR 1 8 2005

Section 6

510(k) Summary

Single Lumen Titanium Implanted Ports

510(k) Summary of Safety and Effectiveness Information
21CFR 807.92

6.1 Submitter Information

Submitter Name:	Bard Access Systems, Inc. (BAS) [Subsidiary of C.R. Bard, Inc.]
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700, Ext. 5541
Fax Number:	(801) 595-5425
Contact Person:	Michaela Rivkowich
Date of Preparation:	February 7, 2005

6.2 Device Name

Device Name:	BardPort® Implanted Port
Trade Name:	Titanium Port, Titanium Low-Profile Port
Catheter:	6.6 Fr and 9.6 Fr Open-Ended Silicone Intravascular Catheters
Common/Usual Name:	Titanium Subcutaneous Port & Catheter
Classification Name:	80LJT – Port & Catheter, Implanted, Subcutaneous, Intravascular 21 CFR 880.5965 – Subcutaneous, Implanted, Intravascular Infusion Port and Catheter, Class II

6.3 Predicate Device Name

Device Name:	BardPort® Implanted Port
Trade Name:	Titanium Port, Titanium Low-Profile Port
Catheter:	6.6 Fr and 9.6 Fr Open-Ended Silicone Intravascular Catheters
Common/Usual Name:	Titanium Subcutaneous Port & Catheter
Classification Name:	80LJT – Port & Catheter, Implanted, Subcutaneous, Intravascular 21 CFR 880.5965 – Subcutaneous, Implanted, Intravascular Infusion Port and Catheter, Class II
Premarket Notification:	K870260, concurrence date – April 15, 1987

6.4 Device Description

Principle of Operation
There are no new operating principles. The Titanium and Titanium Low Profile Ports have the same basic, fundamental scientific technology as the predicate devices. Access to the port is made percutaneously with a non-coring needle that enters the port reservoir via the silicone rubber septum. The access path to the vascular system is provided through a catheter attached to the port. The port system serves as a conduit for fluids into, and out of, the central venous system.

Port

- The Titanium Implanted Port is the largest of the BardPort® single lumen titanium port family. The port body consists of titanium base and top with a round shape design. The port has four suture slots and two suture holes that are silicone encapsulated.
- The Titanium Low Profile Implanted Port is a modified, slightly smaller version of the Titanium Implanted Port. The port body consists of titanium base and top with a round shape design. The port has six unfilled suture holes.

Catheter

- The Titanium Implanted Port is available with attachable or pre-attached 6.6 and 9.6 Fr open-ended silicone intravascular catheters.
- The Titanium Low Profile Port is available with attachable or pre-attached 6.6 Fr open-ended silicone intravascular catheter

6.5 Intended Use

The BardPort® Implanted Ports are totally implantable vascular access devices designed to provide long term repeated access to the vascular system.

6.6 Indications for Use

The BardPort® Implanted Ports are indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples.

6.7 Summary of Technological Characteristics in Relation to the Predicate Device

Does the new device have the same technological characteristics, e.g. design, material, etc.?

Yes with the exception of differences in the catheter depth marking configuration as compared to the predicate Titanium Port with 6.6 Fr and 9.6 Fr open-ended silicone catheters and Titanium Low Profile Port with 6.6 Fr open-ended silicone catheter. However, the basic fundamental scientific technology of the ports has not changed.

Could the new characteristics affect safety or effectiveness?

Yes. The above features could affect safety or effectiveness of the device.

Do the new characteristics raise new types of safety and effectiveness questions?

No. There are no new issues of safety and effectiveness.

Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. The following international standard was used to evaluate the device's performance:

- *ISO 10555-3:1997, Sterile, Single-Use Intravascular Catheters, Central venous catheters*

Biocompatibility requirements of ISO 10993 *Biological Evaluation of Medical Devices Part-1: Evaluation and Testing* and the FDA Modified ISO 10993 Test Profile for a long term implanted device that exhibits tissue contact (port and catheter), indirect blood contact (port)

and direct blood contact (catheter) were met. All materials used in the manufacture of the subject devices were previously cleared for similar applications by Bard Access Systems.

Are performance data available to assess effects of new characteristics?

Yes. Verification testing was performed according to protocols based on the above referenced international standard, as well as in accordance with in-house protocols.

Do performance data demonstrate equivalence?

Yes. Performance data gathered in design verification testing demonstrated that the Titanium and Titanium Low Profile Ports with 6.6 Fr and 9.6 Fr silicone catheters are substantially equivalent to the predicate Titanium and Titanium Low Profile Ports and met predetermined acceptance criteria, and the risks associated with use of the new device were found acceptable when evaluated by FMEA.

Conclusion

The Titanium Port with 6.6 Fr and 9.6 Fr open-ended silicone intravascular catheters and Titanium Low Profile Port with 6.6 Fr open-ended silicone intravascular catheter meet all predetermined performance acceptance criteria of the testing performed and, based on FDA's decision tree, are substantially equivalent to the predicate Titanium and Titanium Low Profile Ports, covered by K870260, concurrence date April 15, 1987.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 8 2005

Ms. Michaela Rivkowich
Senior Regulatory Affairs Specialist
Bard Access Systems, Incorporated
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K050310
Trade/Device Name: Bardport® Single Lumen Titanium Implanted Ports
Regulation Number: 880.5965
Regulation Name: Subcutaneous Implanted Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: April 5, 2005
Received: April 6, 2005

Dear Ms. Rivkowich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

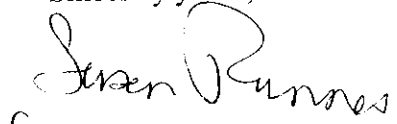
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 1.2

INDICATION(S) FOR USE STATEMENT

510(k) Number (if known): K050310

Device Name: Single Lumen Titanium Implanted Ports

Indications for Use:

The BardPort® Implanted Ports are indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples.

Prescription Use __X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K050310